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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,486	07/29/2002	Marco Turini	112701335	6915
29157	7590	02/27/2004	EXAMINER	
BELL, BOYD & LLOYD LLC P. O. BOX 1135 CHICAGO, IL 60690-1135			PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,486

Applicant(s)

TURINI ET AL.

Examiner

JOHN D PAK

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 2, 16-22 and 26-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6-11, 13-15, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 5, 12 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-40 are pending in this application.

Applicant's election without traverse of the invention of Group I, claims 1, 3-15 and 23-25, in the reply of 12/5/03 is acknowledged. Accordingly, claims 2, 16-22 and 26-40 are withdrawn from further consideration as being directed to non-elected subject matter, and claims 1, 3-15 and 23-25 will presently be examined.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Garleb et al. (US 5,308,832).

Garleb et al. explicitly disclose an enteral nutritional product comprising a lipid blend of n-6 to n-3 fatty acid in the range of 1-6 (including 2 to 4, see claim 17), wherein the lipid provides 70-85% of the calories. See claims 1 and 17. Blending, liquefying and homogenizing steps are disclosed (column 13, Table 7; column 13, line 48 to column 15, line 9). Applicant's claim 3 is thereby anticipated, because all of the claim recited features are expressly disclosed by the cited reference.

Claims 1, 4, 6-9, 11, 13-15, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by DeMichele et al. (WO 94/15464).

DeMichele et al. explicitly disclose a structured lipid that has an n-6 fatty acid selected from the group consisting of gamma-linolenic acid and dihomogamma-linolenic acid, with the two other chains in the triglyceride being selected from the group consisting of an n-3 fatty acid such as alpha-linolenic, eicosapentaenoic, or docosahexaenoic acid and/or C6-12 (medium chain) fatty acid. See claims 1, 7, 16-18; page 1, first paragraph. Since at least one of the chains in the triglyceride is medium chain fatty acids, the percentage is at least 33% (see e.g., the formula in claim 1). There is no other saturated fatty acid after excluding medium chain fatty acids (see again the formula in claim 1). Total calories supplied by the structured lipid is 10-80% (claim 8). Treatment of sepsis is taught (claim 10). Enteral or parenteral administration is taught. Dietary formulation is taught (claims 14-15). Method of making the structured lipid involves known procedures, for example, mixing oils and reacting (page 14, third full paragraph). Clearly, for acceptable formulation such as enteral formulation to be made, liquefying and homogenizing steps are necessarily conveyed. *The claims are thereby anticipated.*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeMichele.

DeMichele et al. disclose a structured lipid that has an n-6 fatty acid selected from the group consisting of gamma-linolenic acid and dihomogamma-linolenic acid, with the two other chains in the triglyceride being selected from the group consisting of an n-3 fatty acid such as alpha-linolenic, eicosapentaenoic, or docosahexaenoic acid and/or C6-12 (medium chain) fatty acid. See claims 1, 7, 16-18; page 1, first paragraph. Total calories supplied by the structured lipid is 10-80% (claim 8). Treatment of a variety of conditions such as trauma, burns, cardiogenic shock, sepsis, endotoxemia, bacteremia, fungemia, adult respiratory distress syndrome is taught (claim 10). Enteral or parenteral administration is taught. Dietary formulation is taught (claims 14-15). Method of making the structured lipid involves known procedures, for example, mixing oils and reacting (page 14, third full paragraph). Clearly, for acceptable formulation such as enteral formulation to be made, liquefying and homogenizing steps are necessarily conveyed.

While DeMichele et al. do not explicitly disclose treating inflammatory shock in verbatim language, one of ordinary skilled artisan would have recognized from treatment of conditions such as trauma, burns, cardiogenic shock, sepsis, endotoxemia, bacteremia, fungemia, adult respiratory distress syndrome that inflammatory shock is encompassed therein. Such traumatic conditions are fairly suggestive of inflammatory

shock. Therefore, one having ordinary skill in the art would have been motivated to utilize DeMichele's composition to treat inflammatory shock, as claimed. As a result, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the cited reference.

Claim 1 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Trimbo (EP 687418).

Trimbo explicitly discloses treating sepsis by administering a dietary composition that contains 10-40 wt% n-6 fatty acids, 10-40 wt% n-3 fatty acids, and less than 60 wt% medium chain triglycerides (claims 1, 5-10; page 3, lines 17-21). One embodiment contains 100% oil or triglycerides, so 100% of the calories come from the lipids in this embodiment (page 3, lines 20-21). The claims are thereby anticipated.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trimbo.

Trimbo discloses treating trauma, burns and/or sepsis by administering a composition that contains 10-40 wt% n-6 fatty acids, 10-40 wt% n-3 fatty acids, and less than 60 wt% medium chain triglycerides (claims 1, 5-10; page 3, lines 17-21). One

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embodiment contains 100% oil or triglycerides, so 100% of the calories come from the lipids in this embodiment (page 3, lines 20-21).

While Trimbo does not explicitly disclose treating inflammatory shock, one of ordinary skilled artisan would have recognized from treatment of trauma and sepsis that inflammatory shock is encompassed therein. Sepsis and trauma are fairly suggestive of inflammatory shock, which is one of septic symptoms. Therefore, one having ordinary skill in the art would have been motivated to utilize Trimbo's composition to treat inflammatory shock, as claimed. As a result, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the cited reference.

Claims 5, 12 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable, subject to a search update at the time of the next Office Action, if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**, **effective February 3, 2004**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

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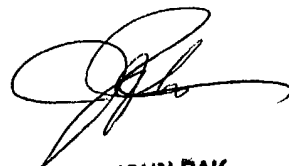
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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Thurman Page, can be reached on (571)272-0602, effective February 3, 2004.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.



JOHN PAK
PRIMARY EXAMINER
GROUP 1000